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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,619	10/07/2004	Rajamannar Thennati	11336.0027USWO	1765

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,619	THENNATI ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/07 has been entered.

Claims 1-21 are pending.

Claim 22 has been cancelled. The rejection of claims 1-7 and 22 under 35 USC 103 over Schumacher et al WO 99/01450 still stands over claims 1-7.

The rejection of claims 1-20 under 35 USC 103 (a) as being obvious over Schumacher et al in view of Villani et al , WO 85/03707 also still stands.

Applicants basically argue that there is no motivation to employ applicants method to eliminate the impurity at retention time .85 to.99 on an HPLC column,

Applicants claim is drawn to a substantially pure Desloratine, not to a process of purifying it.

Applicants claim as written is drawn to a product by process.

The product is the same as that of the prior art.

Purifying a compound to still remove impurities is obvious to a chemist, especially if the compound is used in pharmaceuticals.

Applicants argue that removing a impurity from a compound changes the compounds and may effect the crystallinity of the compound. Additionally applicants submit that weather a chemical

compound has the same usefulness as a prior art compound is only one consideration in establishing obviousness.

Applicants arguments are confusing and not at all convincing.

The claims are drawn to a compound.

Not to a composition.

The claim essentially is drawn to a product by process, however a product of the same purification is well known. The absence of a certain impurity does not give a product any improved property. If applicants compound has less than .5% impurity and a particular impurity is removed, it still has other impurities to make up the .5 %.

Applicants further argue that the composition is different as it does not have the impurity at that particular retention time. Applicants claim is not drawn to a composition but to a compound. A pure compound.

The prior art discloses a pure compound.

Removing a certain impurity from the compound does not make the compound further patentable.

The rejection still stands.

The rejection of claims 1-20 over Schumacher et al in view of Villani et al WO 85/03707 also still stands.

The rejections under 35 USC 112 over claim 22 have been withdrawn as applicants have cancelled the claim.

The examiner is repeating that purifying an old product is prima facie obvious.

As per the MPEP see below , purification of an old known product is not considered to be patentable as mere purity does not render the product unobvious.

The utility is the same as that of desloratadine.

PURIFYING AN OLD PRODUCT

Therefore, the issue is whether claims to a pure material are unobvious over the prior art. *In re Bergstrom*, 427 F.2d 1394, 166 USPQ 256 (CCPA 1970). Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989).
Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966) (Claims to the free-flowing crystalline form of a compound were held unobvious over references disclosing the viscous liquid form of the same compound because the prior art of record did not suggest the claimed compound in crystalline form or how to obtain such crystals.).
See also *Ex parte Stern*, 13 USPQ2d 1379 (Bd. Pat. App. & Inter. 1987) (Claims to interleukin 2 (a protein with a molecular weight of over 12,000) purified to homogeneity were held unpatentable over references which recognized the desirability of purifying interleukin 2 to homogeneity in a view of a reference which taught a method of purifying proteins having molecular weights in excess of 12,000 to homogeneity wherein the prior art method was similar to the method disclosed by appellant for purifying interleukin 2.).
Compare *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (Claims were directed to human nerve growth factor b-NGF free from other proteins of human origin, and the specification disclosed making the claimed factor through the use of recombinant DNA technology. The claims were rejected as *prima facie* obvious in view of two references disclosing b-NGF isolated from human placental tissue. The Board applied case law pertinent to product-by-process claims, reasoning that the prior art factor appeared to differ from the claimed factor only in the method of obtaining the factor. The Board held that the burden of persuasion was on appellant to show that the claimed product exhibited unexpected properties compared with that of the prior art. The Board further noted that "no objective evidence has been provided establishing that no method

was known to those skilled in this field whereby the claimed material might have been synthesized." 10 USPQ2d at 1926.).

Applicants arguments are not found to be persuasive. The compound is the same as that of the prior art.

Applicants are claiming a product by process. The product is still the same.

Applicants claim is drawn to the same compound as that of the prior art.

Applicants claim is not to a composition but to the compound itself.

Thus the rejection still stands.

The rejection of the claims 1-21 under 35 USC 103 0ver Schumacher et al in view of Villani et al WO 85/03707 also still stands. Applicants claims are drawn to the same compounds as those given by Schumacher et al.

Applicants own specifications states
"The PCT application WO 02/42290 claims acid addition salts of desloratadine namely, monoacid, hemiacid and diacid salts. It discloses a process for preparation of diacid salts by reacting loratadine with concentrated mineral acids. It also teaches a process for conversion of diacid salts to monoacid or hemiacid salts by treatment with a solution of a base. It provides new desloratadine hemisulfate salt which is prepared from desloratadine disulfate salt with High Performance Liquid Chromatography (referred to as HPLC herein) purity greater than 99.5% by treatment with a solution of aqueous ammonia. "

Thus desloratadine salts were known to be found in pure.

The properties of the compound are the same. Irrespective of the way it is made.

Applicants also use acid and bases for its purification.

Modifying a process by changing pH and solvents is considered to be prima facia obvious in the absence of unexpected properties.

Thus applicants arguments are not found to be convincing and the rejection still stand.

Conclusion

Claims 1-21 still stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
December 18, 2007